K080232

APR 23 2008

510(k) Summary:

Submitter's Name and Address:

ZOLL Medical Corporation
269 Mill Road
Chelmsford, MA 01824-4105
(978) 421-9655

Contact Person:

Eileen M. Boyle

(978) 421-9171

Date Summary Prepared:

January 23, 2008

Device:

ZOLL E Series 12SL™ Analysis Option

Classification:

Electrocardiograph: Class II (21 CFR 870.2340)

Automatic External Defibrillators: Class III (21 CFR 870.5310)

Description:

The ZOLL E Series products (K042007) combine a defibrillator, ECG Monitor, Noninvasive Transcutaneous Pacing, Pulse Oximetry, End Tidal CO_2 , 12-Lead ECG Monitoring, Non-Invasive Blood Pressure measurement Invasive Blood Pressure and Temperature and data printing and recording in a single instrument.

The 12SL™ Analysis Option using the GE/Marquette 12SL™ Algorithm is useful in the diagnosis of patients with acute myocardial infarction (AMI) and is useful in the interpretation and documentation of other transient cardiac arrhythmias that may occur. The 12-Lead ECG Analysis is indicated for the recording and analysis of 12 Lead ECG signals acquired from adult and pediatric patients in the supine, resting position. The Acute Cardiac Ischemia–Time Insensitive Predictive Instrument (ACI-TIPI) and Thrombolytic Predictive Instrument (TPI) are decision aids for qualified clinicians who may currently wish to calculate ACI–TIPI and TPI in adult patients.

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Intended Use:

The ZOLL E Series with 12SL™ is intended for the recording and automated analysis of 12-Lead ECG signals acquired from adult and pediatric patients in the supine, resting position.

Substantial Equivalence:

The features and functions of the proposed enhancement to the E Series 12SL™ Analysis Option are substantially equivalent to the current features and functions of the E Series 12SL™ Analysis Option (K042007) including the ACI-TIPI feature, cleared for use on 04/07/2005.

Comparison of Technological Characteristics

The ZOLL E Series 12SL™ Analysis Option utilizes the same interpretive features and functions to those of the currently marketed ZOLL E Series 12SL™ Analysis Option (K042007). The device acquires an ECG signal through a 10-wire cable assembly and commonly used patient electrodes placed in a standard 12-Lead configuration. The device is also capable of storing that data to memory and/or transmitting that data via cellular telephone, RS232 port, or wirelessly using Bluetooth™ technology.

Performance Testing:

Extensive performance testing ensures that the ZOLL E Series 12SL™ Analysis Option performs as well as the indicated predicate devices and meets all of its functional requirements and performance specifications. Safety testing assures the device complies with applicable sections of recognized industry and safety standards.

Conclusion

Performance and safety testing of the ZOLL E Series 12SL™ Analysis Option demonstrates that its features and functions are substantially equivalent to those of the indicated commercially distributed predicate devices with regard to performance, safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 23 2008

Zoll Medical Corporation
c/o Ms. Eileen M. Boyle
Regulatory Affairs Specialist
269 Mill Road
Chelmsford, MA 01824

Re: K080232
Trade/Device Name: ZOLL E Series 12SL Analysis Option
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated external defibrillator
Regulatory Class: Class III (three)
Product Code: MKJ
Dated: March 7, 2008
Received: March 27, 2008

Dear Ms. Eileen M. Boyle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4 – INDICATIONS FOR USE

K080132

510(k) Number (if known): _____

Device Name: ZOLL E Series

Defibrillator Function

The E Series products contain a DC defibrillator capable of delivering up to 200 joules of energy. It may be used in synchronized mode to perform synchronized cardioversion by using the R-wave of the patient's ECG as a timing reference. The unit uses paddles or disposable, pre-gelled, MFE Pads for defibrillation.

Intended Use — Manual Operation

Use of the E Series products in the manual mode for defibrillation is indicated on victims of cardiac arrest where there is apparent lack of circulation as indicated by:

- Unconsciousness
- Absence of breathing
- Absence of pulse.

This product should be used only by qualified medical personnel for converting ventricular fibrillation and rapid ventricular tachycardia to sinus rhythm or other cardiac rhythms capable of producing hemodynamically significant heart beats.

Intended Use — Semiautomatic Operation (AED)

The E Series products are designed for use by emergency care personnel who have completed training and certification requirements applicable to the use of a defibrillator where the device operator controls delivery of shocks to the patient.

They are specifically designed for use in early defibrillation programs where the delivery of a defibrillator shock during resuscitation involving CPR, transportation, and definitive care are incorporated into a medically-approved patient care protocol.

The E Series products must be prescribed for use by a physician or medical advisor of an emergency response team.
Use of the device in the Semiautomatic mode for defibrillation is indicated on victims of cardiac arrest where there is apparent lack of circulation as indicated by:

- Unconsciousness
- Absence of breathing
- Absence of pulse.

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K080132

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Indications for Use
(continued from previous page)

Semiautomatic Operation Contraindications for Use

The rhythm analysis function may not reliably identify ventricular fibrillation in the presence of an implantable pacemaker. Inspection of the electrocardiogram and clinical evidence of cardiopulmonary arrest should be the basis for any treatment of patients with implantable pacemakers.

Do not use the rhythm analysis function during patient movement on a stretcher or in an ambulance or other conveyance. A patient must be motionless during ECG analysis. Do not touch the patient during analysis. Cease all movement via stretcher or vehicle prior to analyzing the ECG. If using the device in an emergency vehicle, bring the vehicle to a halt before activating the analysis function.

Defibrillator Complications

Inappropriate defibrillation or cardioversion of a patient (e.g., with no malignant arrhythmia) may precipitate ventricular fibrillation, asystole, or other dangerous arrhythmias.

Defibrillation without proper application of electrode pads or paddle electrolyte gel may be ineffective and cause burns, particularly when repeated shocks are necessary. Erythemia or hypermia of the skin under the paddles or MFE Pads often occurs; this effect is usually enhanced along the perimeter of the paddle or electrode. This reddening should substantially lessen within 72 hours.

External Pacemaker (Pacer Version Only)

Non-invasive Transcutaneous Pacing (NTP) is an established and proven technique. This therapy is easily and rapidly applied in both emergency and non-emergency situations when temporary cardiac stimulation is indicated.

Intended Use – Pacemaker

This product may be used for temporary external cardiac pacing in conscious or unconscious patients as an alternative to endocardial stimulation.

Note: This device must not be connected to internal pacemaker electrodes.

The purposes of pacing include:

Resuscitation from standstill or bradycardia of any etiology:

Noninvasive pacing has been used for resuscitation from cardiac standstill, reflex vagal standstill, drug induced standstill (due to procainamide, quinidine, digitails, b-blockers, verapamil, etc.) and unexpected circulatory arrest (due to anesthesia, surgery, angiography, and other therapeutic or diagnostic procedures). It has also been used for temporary acceleration of bradycardia in Stokes-Adams disease and sick-sinus syndrome. It is safer, more reliable, and more rapidly applied in an emergency than endocardial or other temporary electrodes.

As a standby when standstill or bradycardia might be expected:

Noninvasive pacing may be useful as a standby when cardiac arrest or symptomatic bradycardia might be expected due to acute myocardial infarction, drug toxicity, anesthesia or surgery. It is also useful as a temporary treatment in patients awaiting pacemaker implants or the introduction of transvenous therapy. In standby pacing applications, noninvasive pacing may provide an alternative to transvenous therapy that avoids the risks of displacement, infection, hemorrhage, embolization,

perforation, phlebitis and mechanical or electrical stimulation of ventricular tachycardia or fibrillation associated with endocardial pacing.

Suppression of tachycardia:

Increased heart rates in response to external pacing often suppress ventricular ectopic activity and my prevent tachycardia.

Pacemaker Complications

Ventricular fibrillation will not respond to pacing and requires immediate defibrillation. The patient's dysrhythmia must therefore be determined immediately, so that appropriate therapy can be employed. If the patient is in ventricular fibrillation and defibrillation is successful, but cardiac standstill (asystole) ensues, the pacemaker should be used.

Ventricular or supraventricular tachycardias may be interrupted with pacing but in an emergency or during circulatory collapse, synchronized cardioversion is faster and more certain.

Electromechanical dissociation may occur following prolonged cardiac arrest or in other disease states with myocardial depression. Pacing may then produce ECG responses without evvective mechanical contractions, and other treatment is required.

Pacing may evoke undesirable repetitive responses, tachycardia, or fibrillation in the presence of generalized hypoxia, myocardial ischemia, cardiac drug toxicity, electrolyte imbalance, or other cardiac diseases.

Pacing by any method tends to inhibit intrinsic rhythmicity. Abrupt cessation of pacing, particularly at rapid rates, can cause ventricular standstill and should be avoided.

Noninvasive Temporary Pacing may cause discomfort of varying intensity, which occasionally can be severe and preclude its continued in conscious patients.

Similarly, unavoidable skeletal muscle contraction may be troublesome in very sick patients and may limit continuous use to a few hours. Erythemia or hypermia of the skin under the MFE Pads often occurrs; this effect is usually enhanced along the perimeter of the electrode.

This reddening should substantially lessen within 72 hours.

There have been reports of burns under the anterior electrode when pacing adult patients with severely restricted blood flow to the skin. Prolonged pacing should be avoided in these cases and periodic inspection of the skin is advised.

There are reports of transient inhibition of spontaneous respiration in unconscious patients with previously available units when the anterior electrode was placed too low on the abdoment.

This device must not be connected to internal pacemaker electrodes.

Pediatric Pacing

Pacing can be performed on pediatric patients weighing 33lbs / 15kg or less using special ZOLL pediatric MFE Pads. Prolonged pacing (in excess of 30 minutes), particularly in neonates, could cause burns. Periodic insepction of the underlying skin is recommended.

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Monitor

Intended-Use Multi-parameter Monitoring

This product may be used for monitoring various patient vital signs, including: electrocardiogram (ECG), Pulse Oximetry (SpO2), End Tidal CO2, 12-Lead ECG, and Non-Invasive Blood Pressure (NIBP).

ECG monitoring is indicated by connecting the patient to the unit via the 3 or 5 lead patient cable MFE Pads, or through the paddles.

SpO2 monitoring is indicated for detecting arterial oxygen saturation of blood and pulse rate for adult, pediatric and neonatal patients who are well or poorly perfusing, during both no motion and patient motion conditions.

EtCO2 monitoring is indicated for the continuous measurement of end tidal carbon dioxide (EtCO2) and respiration rate for adult, pediatric and neonatal patients.

12 Lead ECG analysis is indicated for the diagnosis and treatment of adult and pediatric patients with acute myocardial infarction.

NIBP monitoring is indicated for the measurement of arterial blood pressure for resting adult, pediatric, and neonatal patients.